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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,139	07/09/2003	Gary R. Epler	eple0703	2091
23580 7590 11/21/2008 MESMER & DELEAULT, PLLC 41 BROOK STREET MANCHESTER, NH 03104			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 11/21/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,139	<b>Applicant(s)</b> EPLER, GARY R.	
	<b>Examiner</b> JEFFREY G. HOEKSTRA	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 6-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/04/2008 has been entered.

### ***Notice of Amendment***

2. In response to the amendment(s) filed on 09/04/2008, amended claim(s) 1 and cancelled claims 20-53 is/are acknowledged. The current rejections of the claim(s) 1-3 and 5 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: the positive recitation of "the potential" in line 1 should apparently read "a potential". Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the positive recitation of "the identification" in lines 2-3 should apparently read "an identification". Appropriate correction is required.

5. Claim 1 is objected to because of the following informalities: the positive recitation of "the probability" in line 21 should apparently read "a probability".

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millenson (EP 0 717 283 A2) in view of Terra et al. (see attached Abstract of Pharmacogenetics, pharmacogenomics, and cardiovascular therapeutics: the way forward, 2002, American Journal of Cardiovascular Drugs 2(5):287-296., hereinafter Terra).

8. For claims 1-3 and 5, Millenson discloses a diagnostic and directed medication system (100) that is capable of minimizing a potential adverse drug reaction to a prescribed medical therapy based upon the identification of predefined drug metabolism risk markers, said system comprising:

- a drug metabolism test component (10) comprising a medical sample receiving apparatus (40) having at least a first sample holding pad (50) configured to receive a user's biological sample (column 4 lines 21-54), said first sample holding pad being capable of preserving the user's biological sample for later identification and testing of the presence of one or more predefined drug metabolism markers that are

capable of indicating the potential adverse drug reaction to the prescribed medical therapy; and

- a written prescription instruction component (120) containing a first instruction that is capable of directing a user to obtain said drug metabolism test component and to follow the a test component instruction of said drug metabolism test component to obtain said user's biological sample and to submit the sample for testing to obtain a test result (column 5 lines 15-42), and a second instruction that is capable of directing said user on how to obtain a prescribed medical therapy containing a prescription for a medication based on the test result of the drug metabolism test component wherein said medication is selected based on the test result to minimize a probability of causing the adverse drug reaction when said medication is taken by the user (column 5 lines 15-42), wherein said second instruction is capable of further directing said user to present said test result to a healthcare provider to obtain said prescribed medical therapy containing a prescription for the medication selected based on the test result to minimize the probably of causing said adverse drug reaction when said medication is taken by said user (column 5 lines 15-42).

9. Millenson discloses the claimed diagnostic and directed medication system, as set forth and cited above, except for expressly disclosing the drug metabolism test component and written prescription instruction are configured to minimize the probability of adverse drug reactions to a prescribed medical therapy and prescription thereof based upon an identification of one or more predefined drug metabolism risk markers that predict a high probability of organ dysfunction in a user's biological sample, wherein

the one or more predefined drug metabolism markers are DNA and the drug metabolism test component is a genomics-based test.

10. Terra teaches (Abstract) prescribing drugs and medical therapies to patients based on their individual biological markers comprising an identification of one or more predefined drug metabolism risk markers in a DNA-based manner using genomics-based testing to minimize the probability of adverse drug reactions that may inherently cause a high probability of organ dysfunction.

11. The claimed invention would have been obvious because a particular known technique was recognizes as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of prescribing drugs and medical therapies to patients based on predefined drug metabolism risk markers in a DNA-based manner using genomics-based testing to minimize the probability of adverse drug reactions as taught by Terra to improve the directed medication system of Millenson for the achieving the predictable result of providing a medical diagnostic and prescription system that increases patient safety by minimizing adverse drug reactions based on a patients physiological makeup.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-3 and 5 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736